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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,149	11/01/2000	William F. Swain	APF 34.20	4573
22428	7590	02/23/2006	EXAMINER	
FOLEY AND LARDNER LLP			LI, BAO Q	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1648	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/705,149

Applicant(s)

SWAIN ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 22-26, 31-34 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 22-26, 31-34 and 52 is/are rejected.
- 7) ☒ Claim(s) 15-17, 22-26, 31-34 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2005 has been entered. The RCE follows:

Response to Amendment

This is a response to the amendment filed 12/14/05. Claims 15, 17, 22, 23, 26, 31, 32 have been amended. New claim 52 has been added. Claims 15-17, 22-26, 31-34 and 52 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Matter Objection

The amendment filed on 12/14/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials, which are not supported by the original disclosure is as follows: (1). In claim 15, lines 3-4: “ wherein each vector construct carries non-overlapping HSV genomic DNA fragments”, and (2). Claim 52, the method of claim 15, wherein said non-overlapping genomic DNA fragment obtained from HSB have at least 95% homology to nature genomic fragment obtained from HSV.

Applicant is required to cancel the new matter in the reply to this Office Action.

New matter Rejection

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1648

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-17, 22-26, 31-34 and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claim 15, lines 3-4 contains a new matter set forth below: “ wherein each vector construct carries non-overlapping HSV genomic DNA fragments”, and (2). Claim 52 also contains a new matter, which cites that “the method of claim 15, wherein said non-overlapping genomic DNA fragment obtained from HSB have at least 95% homology to nature genomic fragment obtained from HSV.” All of these new matters are not supported by the specification as is was originally filed.
3. While applicants assert in the response that support for the amendment can be found on page 13, lines 13-28 and page 18, line 19.
4. The disclosures of page 13 and page 18 have been carefully reviewed; however, they are not found to be the support of the new amendment, i.e. the specification does not teach or disclose that each vector constructor administered into an vertebrate comprises non-overlapping HSV genomic DNA fragment, wherein said HSB have at least 95% homology to nature genomic DNA fragment obtained from HSV.
5. Applicants are required to cancel the new matters to overcome the rejection.

Claim Rejections - 35 USC § 103

6. The 103 rejection for claims 15-17, 22-24, and 31-34 are moot in view of new ground rejection as stated above. However,, if applicants cancel the new matter, the rejection is still apply.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1648

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 15-17, 22-26, 31-34 and 52 are still rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicants only disclose to use a DNA vector as a DNA vaccine for eliciting an immune response, Applicants do not have a possession for more than one vectors to delivery more than one pathogens DNA fragments.

9. Applicants argue that the claim 15 now amended to be core carries coated with vector constructs. Moreover, applicants point out HSV gD or gB disclosed by the specification has molecular weight of 1180 or 2101, which are all packed with more than size of 5 or 25 Kd by plasmid and cosmid, therefore, the rejection should be withdrawn.

10. Applicants' argument has been fully considered; however, it is not fond persuasive to overcome the rejection because the outstanding rejection is that the specification does not described use more than one kinds of vectors simultaneously administered into a subject to induce an immune response against HSV. Moreover, the specification also fails to provide the support teaches that each of the non- overlapping sequences of HSV carried by a vector constructs have 95% homology to the nature HSV genome, but none of them overlaps each other. Still further, applicants do not disclose that the composition administered into a subject comprises the vector constructs as mixture and each of them differs in packaging with structurally non-overlapping HSV genomes respectively. Hence, the rejection is still maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER
Baoqun Li
Bao Qun Li
02/22/2006